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(54) SILVER IMPREGNATED CONTACT LENS

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The following information was taken from documents submitted by the applicant.

A request for an examination pursuant to § 44 PatG has been submitted.

(57) In order impregnate a hydrogel contact lens permanently with silver for antimicrobial purposes, it is proposed to treat the contact lens first with a silver nitrate solution and then with a sodium dithionite solution, with precipitation of silver sulfide. The precipitated silver sulfide

binds sufficiently strongly with the hydrogel so that it does not diffuse out of the hydrogel even following steam sterilization and long-term storage in a saline solution.

Description

[0001]

The invention relates to a silver impregnated contact lens as well as to a method for impregnating such a contact lens with silver.

[0002]

Contact lenses, particularly soft, porous, oxygen permeable contact lenses made of a hydrogen material that are capable of swelling while maintaining their shape, are particularly susceptible to contamination by microbes, such as viruses, bacteria and fungi, which colonize not only the surface of the lens but also in the interior of the lens material, and thus can reach the eye. Following prolonged use, microbes can colonize and multiply between the contact lens and the cornea, potentially leading to severe eye infections. As a preventive measure, contact lenses are therefore stored in an antimicrobial solution when not used. It has also been attempted to impregnate the contact lenses themselves with silver to protect them from microbial growth even while they are being used.

[0003]

Thus, it is known from DE-A-41 23 893 to incorporate an antibacterial, silver containing ion exchanger based on ceramics, particularly hydroxylapatite, in the contact lens material, or to apply it to the surface of the finished contact lens. However, this has the drawback of making the lens surface uneven. Moreover, the lens itself can become opaque and turn turbid. In addition, the method is expensive.

[0004]

From WO89/02498 it is known that spraying the external side of a hydrogel contact lens with a silver nitrate solution, for cosmetic purpose only, followed by immersion of the lens in a saline solution precipitates the silver. After exposure to light, a visible silver salt precipitate forms on the external side, which leads to an opaque coloration of the contact lens under exposure to light. The silver precipitate so obtained is resistant to the lachrymal fluid and to the repeated closing and opening of the eye lids; however, over time, particularly in the case of storage in a saline solution or in the case of steam sterilization, the precipitate can separate from the contact lens and it is consequently not always sufficiently preserved over time.

[0005]

US 4 634 449 discloses a similar method, in which a hydrogel contact lens is treated with silver nitrate and the silver is precipitated using a salt solution in the form of a silver salt, where the goal again is only to color the contact lens visibly, for cosmetic reasons. An additional purpose here is to reduce light transmission to increase the vision comfort of the wearer, similarly to sunglasses.

[0006]

Finally, from GB 2 202 962, a method is known to produce opaquely colored areas in hydrogel contact lenses by treating the contact lens with silver nitrate followed by precipitation of the silver with ascorbic acid or formaldehyde.

[0007]

R. Schweissfurt and B. Wunn, in Kontaktologia 7D (1985), pp. 144-147, describe the use of silver in contact lens containers. Here a description is provided indicating that by storing the contact lenses in silver-coated containers and/or by adding silver wool to the storage containers, test organisms can be killed, which made it possible to store the contact lenses without the use of a preservative.

[0008]

However, it has been shown that these methods are not appropriate for conferring sufficient sterility to a contact lens on a permanent basis. Therefore, the problem of the invention is to provide a contact lens with permanent persistent antimicrobial properties, as well as a method for manufacturing such a contact lens. An additional goal of the invention is to provide such contact lenses, in which the antimicrobial fitting does not color the lens or does not color it in a perceptible manner.

[0009]

This problem is solved according to the invention by a silver impregnated contact lens, in which the silver is present in the hydrogel matrix in an amorphous form or as a sparsely soluble silver salt in an extremely fine distribution.

[0010]

Indeed, it was unexpectedly found that it is possible to fit the contact lens permanently with antimicrobial properties, providing "life long" protection under the conditions of use and with respect to the duration of use if one impregnates the contact lens with a soluble silver salt in

such a manner that the silver is located not only on the surface and the near-surface areas or layers, but also completely impregnates the hydrogel matrix, and if a precipitation reagent is used to precipitate the soluble silver salt which is distributed in the hydrogel to form a sparsely soluble or insoluble silver salt. In this manner, the silver is immobilized in the matrix without losing its antimicrobial efficacy.

[0011]

It is preferred here for the solubility of the silver salt to be not greater than that of silver chloride. Preferred precipitation reagents here are halide and/or sulfide salts, where the sulfides are particularly preferred. Typical precipitation reagents here are alkali and alkaline earth halides, particularly chlorides, bromides and iodides, such as sodium and potassium chloride, calcium chloride and magnesium chloride. Typical sulfides are pure hydrogen sulfur as well as metal sulfides which sparsely precipitate soluble silver sulfides, such as, for example, sodium sulfide. Using this procedure, a silver salt which is extremely finely distributed in the hydrogel matrix, particularly silver sulfide or silver halides, is obtained where the halides decompose at least partially to amorphous silver when exposed to light. Such contact lenses which are fitted with amorphous silver also present an antimicrobial effect.

[0012]

It has now been unexpectedly found that the microbial fitting so obtained is firmly incorporated in the contact lens matrix so that, even after long-term use, including long-term storage in a salt containing care fluid, it does not separate out of the contact lens and does not lose its antimicrobial efficacy. In contrast to conventional silver ion-containing contact lenses, a contact lens according to the invention can even be sterilized with steam without the silver salt separating out of the contact lens. In this manner, one obtains a "life long" active antimicrobial silver impregnation of the contact lens. In contrast to conventional contact lenses, lenses which have been fitted according to the present invention, do not require, as a rule, continuous antimicrobial re-treatment, for example, in an antimicrobial storage fluid when they are not being used.

[0013]

It is preferred to use the silver in the form of silver salt, particularly silver nitrate, which is diffused into the contact lenses and then precipitated using a sulfur containing compound, particularly sodium dithionite and/or sodium sulfide. In the process, a mixture of water insoluble silver compounds is produced, namely silver sulfide as well as also silver oxide and pure silver.

[0014]

Particularly, lasting antimicrobial properties are produced if the silver sulfide content of the total silver in the lens is at least 10-90 mol%; and, in the case of precipitation of silver sulfide from silver nitrate with sodium sulfide, if it is 10-100 mol%.

[0015]

If the silver is to be introduced exclusively as an antimicrobial active ingredient into a contact lens which is used only for purposes of optical correction, it is sufficient to use a total silver concentration which does not visibly color the contact lens. If the eyes are to have a darker appearance for cosmetic reasons, the silver concentration can also be increased, while the contact lens is still transparent overall.

[0016]

Depending on the application purpose, in the case of precipitation of silver sulfide, particularly if the silver concentration is visible, the impregnation can also form lasting persistent partial markings or patterns, for example, cosmetic patterns which, for example, give the eyes the appearance of "radiating" or which enhance natural eye color or give it the appearance of another color. Optionally, it is also possible to use, impregnation with higher concentration to produce visible marks, letters, images, writing or identification numbers in the lens in addition to the surface covering silver impregnation of the lens. For this purpose, the silver salt and/or the precipitating reagent can be applied in patterns, for example dots, or by sputtering.

[0017]

An inventive antimicrobial impregnation method for a contact lens, particularly a hydrogen contact lens, is comprised of the steps:

A) treatment of the contact lens with silver salt, particularly silver nitrate, and then

B) treatment of the contact lens with a halogen containing and/or sulfur containing compound, particularly with sodium dithionite and/or sodium sulfide, for the formation of silver dithionite or silver sulfide.

[0018]

It is preferred to treat the contact lens with silver salt in the nonswollen state, which makes it possible – depending on the pH – to shorten the treatment duration to from one second to two minutes. In principle, this treatment step is also possible with swollen contact lenses, although a substantially longer treatment duration is necessary, approximately 0.5-2 h.

[0019]

To obtain a visible impregnation it is preferred to treat a contact lens with a 0.001-0.5 wt%, more advantageously 0.01-0.1 wt%, and particularly with a 0.02-0.06 wt% silver nitrate solution, where a 0.03-0.05 wt% solution is particularly preferred.

[0020]

In the case of swollen lenses, it is also possible to use much higher, approximately 10-30 wt% concentrations; in this case for the purpose of not excessively extending the treatment duration. It is preferred to immerse the contact lens in a silver salt solution, however, the silver salt can also be applied by spraying, depending on the application case.

[0021]

To precipitate the silver sulfide or halide, it is preferred to immerse the contact lens in a halide containing and/or sulfide containing solution, however, it is also possible to apply a spray treatment. The silver sulfide, halide or oxide, or the amorphous silver which is precipitated by the treatment binds sufficiently firmly in the hydrogel so that it remains in the contact lens even after steam sterilization, for example, at a temperature of 110-120°C for 15-20 min, and even after months of storage in a 0.9% saline solution. Even after a longer storage, for example, for one year, the lens keeps its silver impregnation and it remains sterile without retreatment. Additional antimicrobial care agents are not necessary, which again reduces the stress on the eye because it does not come in contact with such care agents, and as a result allergies can be prevented.

[0022]

The invention is explained below with reference to preferred embodiments.

Example 1

[0023]

On the surface of a dry hydrogel contact lens of the Weflex 55 type (55% water content, nonionic, Company Wöhlk, Kiel/Germany), 30 µL of a 0.0425 wt% aqueous silver nitrate solution (Fluka No. 10220) are applied with the aid of a micropipette and allowed to soak at room temperature. The excess solution was then allowed to run off or removed by blotting. As the developer, the same quantity of a 4.5 wt% aqueous sodium sulfide solution (Merck No. 106638) was then applied to form silver sulfide.

[0024]

The excess solution was again allowed to drip off or removed by blotting, and then it was re-rinsed twice with isotonic saline solution.

[0025]

The impregnated lenses were then swollen, steam sterilized and packaged.

Example 2

[0026]

The same procedure as in Example 1 was used, except that instead of using sodium sulfide solution as the developer, a 4.50 wt% aqueous sodium dithionite solution (Merck No. 106507) was applied for the formation of silver dithionite and, due to the reduction of Ag^+, elemental silver.

Example 3

[0027]

The same procedure was used as in Example 1, except that instead of using sodium sulfite solution as the developer, 4.50 wt% sodium hydroxide solution (Merck No. 106495) was used to form silver oxide.

Example 4

[0028]

The same procedure as in Example 1 was used, except that a 0.425 wt% silver nitrate solution was used. After 30 sec of the action of silver nitrate solution and 45 sec of the action of sodium sulfide, a deep brown lens was produced. When the time of exposure was decreased in increments to 1 sec silver nitrate solution and 1 sec sodium sulfide, the lens produced was still slightly brown.

[0029]

If a silver nitrate solution is diluted 10-fold (to 0.0425 wt%), 15, 10 and 5 sec of action of the silver nitrate solution and correspondingly 15, 10 and 5 sec sodium sulfide each produced colorless lenses.

[0030]

As in the examples, the developer can be used singly, or several different developers can be used in a mixture.

[0031]

For comparison, the effect of the inventive silver impregnated and steam sterilized hydrogel contact lenses on Pseudomonas aeruginosa and Staphylococcus aureus was tested by comparison to otherwise identical conventional lenses which had not been treated with silver.

[0032]

The silver treated and untreated lenses each were incubated in a microbe suspension. Immediately thereafter, the corresponding formed colony unit count on the lenses was not different.

[0033]

After incubation for 6 hours in 0.9% sodium chloride solution at 25°C, the colony forming unit count for Pseudomonas aeroginosa was decreased by four powers of ten and that of Staphylococcus aureus by one power of ten compared to the untreated lenses. After 24 h of storage, the antimicrobial effect was even clearer: the colony forming unit count for Pseudomonas aeruginosa on the silver treated lens was decreased by six powers of ten, while in the case of Staphylococcus aureus the decrease was by 1.5 power of ten.

[0034]

It is known from the literature that the yeast Candida albicans has a sensitivity to silver ions which is similar to that of Pseudomonas aeruginosa, so that one can expect that the silver treatment of the contact lenses has a similar effect against Candida albicans as against Pseudomonas aeroginosa.

Claims

1. Silver impregnated contact lens, particularly hydrogel contact lens, comprised of a lens body formed from a porous matrix, characterized in that the silver in the matrix is at least in part in the form of a sulfide, halide, oxide and/or in amorphous form.

2. Contact lens according to Claim 1, characterized in that the silver diffuses in the form of silver salt, particularly silver nitrate, into the contact lens, and then it is precipitated with a sulfur containing compound, particularly sodium sulfide, as silver sulfide.

3. Contact lens according to Claim 1 or 2, characterized in that the silver is in the form of a mixture of silver oxide, silver sulfide and pure silver.

4. Contact lens according to one of the preceding claims, characterized in that the proportion of the silver in the lens is at least 10 mol%.

5. Contact lens according to one of the preceding claims, characterized in that overall the silver is present at a concentration which does not visibly color the contact lens.

6. Contact lens, particularly hydrogel contact lens according to one of the preceding claims, characterized in that it is impregnated, at least on its side which is turned toward the eye, with distribution over the entire surface with silver precipitated from a solution or with a precipitated silver compound.

7. Method for the antimicrobial impregnation of a contact lens, particularly a hydrogel contact lens, with the steps:

A) treatment of the contact lens with silver salt, particularly silver nitrate, and then

B) treatment of the contact lens with a halide containing and/or sulfide containing compound, with precipitation of silver sulfide.

8. Method according to Claim 7, characterized in that step A) is carried out with a non-swollen hydrogel contact lens.

9. Method according to Claim 7 or 8, characterized in that a 0.01-0.1 wt% silver nitrate solution is used in step A).

10. Method according to one of Claims 7-9, characterized in that the contact lens is immersed in a silver salt solution in step A).

11. Method according to one of Claims 7-10, characterized in that the contact lens is treated with sodium sulfide in step B).

12. Method according to one of Claims 7-11, characterized in that the contact lens is treated with sodium dithionite solution in step B).

13. Method according to one of Claims 7-12, characterized in that the contact lens is treated with sodium hydroxide solution in step B).